

**AMENDMENTS TO THE CLAIMS**

In accordance with Rule 1.121, a complete claim listing is presented below, including appropriate status identifiers. Changes in the amended claims are shown by strikethrough for deleted material, and by underlining for added material.

1-83. (Cancelled)

84. (Currently Amended) A method for validating a treatment process for reducing the amount or activity of a contaminating biological agent in a sample, comprising:

(i) exposing an indicator and the contaminating biological agent to the treatment process,

wherein the indicator is a thermostable kinase,

the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides and prions, and

the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, [[and]] gas-phase sterilant, and high-temperature autoclaving with steam;

(ii) measuring residual kinase activity of the thermostable kinase after the treatment; and

(iii) comparing said residual kinase activity of the thermostable kinase to the kinase activity of the thermostable kinase before the treatment;

wherein a reduction in the kinase activity of the thermostable kinase after the treatment, as compared to the kinase activity of the thermostable kinase before the treatment, can be correlated with a reduction in the amount or activity of the contaminating biological agent.

85. (Previously Presented) The method of Claim 84, wherein the thermostable kinase is immobilised as part of a solid support.

86. (Previously Presented) The method of Claim 84, wherein the thermostable kinase comprises adenylate kinase, acetate kinase or pyruvate kinase.

87. (Previously Presented) The method of Claim 85, wherein the solid support comprises an indicator strip, a dip stick or a bead.

88. (Previously Presented) The method of Claim 84, wherein the contaminating biological agent comprises a transmissible spongiform encephalopathy.

89. (Previously Presented) The method of Claim 84, wherein the thermostable kinase has an amino acid sequence selected from the group consisting of SEQ ID Nos:1-25.

90. (Previously Presented) The method of Claim 84, wherein the thermostable kinase is encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos:26-30.

91-96. (Cancelled)

97. (Currently Amended) A method for validating a treatment process, comprising:

(i) obtaining a sample that may contain a contaminating biological agent[[;]],  
wherein the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides and prions;  
and

(ii) exposing a mixture comprising the sample and a defined amount of a thermostable kinase to the treatment process, wherein the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, gas-phase sterilant, and high-temperature autoclaving with steam; wherein the treatment process reduces an amount or activity of the contaminating biological agent;

(iii) measuring a residual kinase activity and optionally calculating a reduction in kinase activity; and

(iv) comparing said residual kinase activity to a predetermined kinase activity, or comparing said reduction in kinase activity to a predetermined reduction in kinase

activity, wherein the predetermined kinase activity or predetermined reduction in kinase activity corresponds to a confirmed reduction in the amount or activity of the contaminating biological agent under identical treatment process conditions,

~~wherein the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides and prions; and~~

~~the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, gas phase sterilant.~~

98. (Currently Amended) The method of Claim 97, wherein the infectious contaminating biological agent comprises a transmissible spongiform encephalopathy.

99. (Previously Presented) The method of Claim 97, wherein the thermostable kinase comprises an adenylate kinase, an acetate kinase or a pyruvate kinase.

100. (Previously Presented) The method of Claim 97, wherein the thermostable kinase has an amino acid sequence selected from the group consisting of SEQ ID Nos:1-25.

101. (Previously Presented) The method of Claim 97, wherein the thermostable kinase is encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos:26-30.

102. (Currently Amended) A method of correlating the reduction in the amount or activity of a contaminating biological agent in a sample with the thermostable kinase activity of the activity of a biological process indicator according to Claim 91, comprising:

(i) preparing a first sample comprising a defined amount of the contaminating biological agent and a second sample containing a defined amount of the thermostable kinase;

(ii) subjecting the first and second samples to a treatment process comprising an exposure to at least one member selected from the group consisting of pH,

temperature, pressure, enzyme, detergent, chemical sterilant, ~~and gas-phase gas-phase sterilant, and high-temperature autoclaving with steam;~~

- (iii) measuring the residual kinase activity of the thermostable kinase and optionally calculating the reduction in kinase activity;
- (iv) measuring residual amount or activity of the contaminating biological agent and optionally calculating the reduction in the amount or activity of the contaminating biological agent; and

(v) repeating steps (i) to (iv), wherein at least one parameter of the treatment process is changed;

wherein the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides and prions.

103. (Previously Presented) The method of Claim 102, wherein the contaminating biological agent comprises a transmissible spongiform encephalopathy.

104. (New) A method for validating a treatment process for reducing the amount or activity of a contaminating biological agent in a sample, comprising:

(i) directly exposing an indicator and the contaminating biological agent to the treatment process,

wherein the indicator is a thermostable kinase,

the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides and prions, and

the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, gas-phase sterilant, and high-temperature autoclaving with steam;

(ii) measuring residual kinase activity of the thermostable kinase after the treatment; and

(iii) comparing said residual kinase activity of the thermostable kinase to the kinase activity of the thermostable kinase before the treatment;

wherein a reduction in the kinase activity of the thermostable kinase after the treatment, as compared to the kinase activity of the thermostable kinase before the treatment, can be correlated with a reduction in the amount or activity of the contaminating biological agent.

105. (New) A method for validating a treatment process, comprising:

(i) obtaining a sample that may contain a contaminating biological agent, wherein the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides and prions; and

(ii) directly exposing a mixture comprising the sample and a defined amount of a thermostable kinase to the treatment process, wherein the treatment process comprises an exposure to at least one member selected from the group consisting of pH, temperature, pressure, enzyme, detergent, chemical sterilant, gas-phase sterilant, and high-temperature autoclaving with steam; wherein the treatment reduces an amount or activity of the contaminating biological agent;

(iii) measuring a residual kinase activity and optionally calculating a reduction in kinase activity; and

(iv) comparing said residual kinase activity to a predetermined kinase activity, or comparing said reduction in kinase activity to a predetermined reduction in kinase activity, wherein the predetermined kinase activity or predetermined reduction in kinase activity corresponds to a confirmed reduction in the amount or activity of the contaminating biological agent under identical treatment process conditions.

106. (New) A method of correlating the reduction in the amount or activity of a contaminating biological agent in a sample with thermostable kinase activity of a biological process indicator, comprising:

(i) preparing a first sample comprising a defined amount of the contaminating biological agent and a second sample containing a defined amount of the thermostable kinase;

(ii) subjecting the first and second samples to a treatment comprising direct exposure to at least one member selected from the group consisting of pH,

temperature, pressure, enzyme, detergent, chemical sterilant, gas-phase sterilant, and high-temperature autoclaving with wet or dry steam;

(iii) measuring the residual kinase activity of the thermostable kinase and optionally calculating the reduction in kinase activity;

(iv) measuring residual amount or activity of the contaminating biological agent and optionally calculating the reduction in the amount or activity of the contaminating biological agent;

(v) repeating steps (i) to (iv), wherein at least one of the treatment parameters is changed; and

wherein the contaminating biological agent comprises at least one member selected from the group consisting of bacteria, viruses, spores, proteins, peptides and prions.

107. (New) The method of Claim 104, wherein the contaminating biological agent comprises a transmissible spongiform encephalopathy.

108. (New) The method of Claim 104, wherein the thermostable kinase has an amino acid sequence selected from the group consisting of SEQ ID Nos:1-25.

109. (New) The method of Claim 104, wherein the thermostable kinase is encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos:26-30.

110. (New) The method of Claim 105, wherein the contaminating biological agent comprises a transmissible spongiform encephalopathy.

111. (New) The method of Claim 105, wherein the thermostable kinase comprises an adenylate kinase, an acetate kinase or a pyruvate kinase.

112. (New) The method of Claim 106, wherein the contaminating biological agent comprises a transmissible spongiform encephalopathy.